UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Merck & Co., Inc., and MSD Technology L.P., Plaintiffs, v. Mediplan Health Consulting, Inc., d/b/a rxnorth.com, Defendant.	Civil Action No. 05 CV 3650 (DC) (FM)
Merck & Co., Inc., and MSD Technology L.P., Plaintiffs, v. North Pharmacy Inc., and PPI Pivotal Partners Inc., d/b/a canadapharmacy.com, Defendants.	Civil Action No. 05 CV 3696 (DC) (FM)
Merck & Co., Inc., and MSD Technology L.P., Plaintiffs, v. Universal Drug Store LTD, d/b/a universaldrugstore.com, Defendant.	Civil Action No. 05 CV 3698 (DC) (FM)

DEFENDANTS' MEMORANDUM
IN SUPPORT OF MOTIONS TO DISMISS COUNTS II *ET SEQ.*

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Defendants submit this memorandum in support of their motions under Rule 12(c), F.R.Civ.P, to dismiss Counts II *et seq.* of Plaintiffs' complaints in the three above-captioned actions.

I. SINCE MERCK'S PLEADING CONCEDES THAT CONSUMERS KNOWINGLY ORDER THEIR PRESCRIPTION DRUGS FROM CANADA, MERCK'S "MISREPRESENTATION" CLAIMS ARE DUE TO BE DISMISSED

Merck pleaded:

> "In the United States, ZOCOR patients who have purchased their medication in pharmacies located in this country are aware that there is no available FDA approved generic substitute for Merck's ZOCOR product, that the only available FDA approved simvastatin product in the United States is ZOCOR brand simvastatin, and that this product originates from or is sponsored and approved by a single source of origin, namely Merck. Thus, *these patients understand that only Merck's ZOCOR brand simvastatin product can be lawfully sold in the United States.*"[1]

Hence, Merck pleads (contrary to its own interest) that U.S. patients who decide to order prescription drugs from Canada, do so with knowledge that Canadian drugs are not approved U.S. drugs. No one who ordered such drugs could be "misled"; rather, U.S. patients order from Canada for the precise reason that U.S. drugs are too expensive. It is the high price of U.S. drugs that causes U.S. patients to look elsewhere to meet their prescription drug needs and leads them to order from Canadian pharmacies. Rather than being "misled", these U.S. patients are pleased to be able to obtain quality drugs to meet their health needs, at an affordable price.[2]

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[1] Complaint, Case No. 3698, Par. 47 (emphasis added) (the same passage is included in each of these three cases, with varying paragraph numeration).

[2] As testified by Dr. Georges C. Benjamin of the American Public Health Association (APHA):

> "You go into a hospital or you go to your doctor, and they do a marvelous thing for you, and then they write you a prescription for something which will save your life, and you can't afford it, and the choices that you have to make are unacceptable: food, rent, medication. So in essence, dying from

Merck's pleading is therefore defective for failure to meet the materiality requirement of *NBA v. Motorola*, 105 F.3d 841, 855 (2 Cir. 1997) (emphasis added):

> [P]laintiff must also show that the defendants "misrepresented an 'inherent quality or characteristic'" of the product. *National Assoc. of Pharmaceutical Mfrs. v. Ayerst Lab.*, 850 F.2d 904, 917 (2d Cir.1988) . . . This requirement is essentially one of materiality, a term explicitly used in other circuits. *See American Tel. & Tel. Co. v. Winback and Conserve Program, Inc.*, 42 F.3d 1421, 1428 n. 9 (3d Cir.1994) (plaintiff alleging false advertising must prove "that the deception is material in that it is likely to influence purchasing decisions") (citations and internal quotation marks omitted), *cert. denied*, 514 U.S. 1103, 115 S.Ct. 1838, 131 L.Ed.2d 757 (1995); *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 964 (D.C.Cir.1990) (false or misleading ads must be "material in their effects on buying decisions"); *Taquino v. Teledyne Monarch Rubber*, 893 F.2d 1488, 1500 (5th Cir.1990) (deception must be "material, in that it is likely to influence the purchasing decision"); *see also* 3 MCCARTHY ON TRADEMARKS § 27:35 at 27-54 (*there must be "some showing that the defendant's misrepresentation was 'material' in the sense that it would have some effect on consumers' purchasing decisions.*").

Since Merck has conceded that "patients *understand* that only Merck's ZOCOR brand simvastatin product can be lawfully sold in the United States", it is undisputed on the pleadings that the legality *vel non* of defendants' products for sale in the U.S. is no material factor in the patients' decision to have purchased these products from Canada. Rather, the purchase decision is price-driven: consumers order from Canada due to high cost in the United States.

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> starvation, dying from being too hot or too cold, or dying from lack of effective therapeutics. Those are not choices that patients ought to make, certainly not in the United States of America." *HHS Task Force on Drug Importation Listening, Session #1: Consumer Groups, March 19, 2004* (http://www.hhs.gov/importtaskforce/session1/listening.html).

In the *NBA* case, the Second Circuit went on to hold:

> The district court found, "[a]fter viewing the complained-of statements in this action in their context," that "[t]he statements as to the particular origin of game updates constitute nothing more than minutiae about SportsTrax." 939 F. Supp. at 1110. We agree with the district court that the statements in question are not material in the present factual context. The inaccuracy in the statements would not influence consumers at the present time, whose interest in obtaining updated game scores on pagers is served only by SportsTrax. Whether the data is taken from broadcasts instead of being observed first-hand is, therefore, simply irrelevant. *NBA*, 105 F.3d at 855.

Here, Merck's supposed key issue of misrepresentation under Lanham Act §43(a)—whether Canadian drug factories are *technically licensed* by the FDA to be approved U.S. drug factories[3]—is the same kind of "minutiae" that the *NBA* court held to have been properly disregarded by the district court in rejecting NBA's complaint about the exact source of the information broadcast on Motorola's unauthorized sports-score pagers.

Merck cannot now make an issue in its briefs where none exists in its pleadings; and Merck nowhere has pled that any concrete harm to consumers has resulted from the accused imported drugs (which on these pleadings must be accepted to be safe and effective (as in fact they are)). Since Merck concedes that consumers understand what they are doing when they order drugs from Canada, its claims of misrepresentation by defendants are due to be dismissed on the pleadings.[4]

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[3] Hearing Transcript, June 27, 2005, p. 4, lines 18-24.

[4] Merck's counts under both Federal and N.Y. State unfair competition law should be dismissed for these reasons. Since defendants filed their Answers, Merck may not now amend its Complaints without leave of Court on motion.

II. THE LANHAM ACT IS NOT A "WILD CARD" FOR PRIVATE ENFORCEMENT OF ADMINISTRATIVE REGULATIONS

FDA grants discretion to its officers to *permit* importation of prescription drugs by individual patients, which they have ordered from foreign countries:

> When personal shipments of drugs and devices that appear violative are brought to FDA's attention by Customs, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product.
> http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html

It stands to reason that the shipments in issue here, have *not* been detained by the FDA—or else Merck would not be complaining about them before this Court. Merck may not deal itself a presumed authority to act as a private FDA, counter to the FDA's discretion to permit drug importation for personal use, by invoking the Lanham Act as a wild card.

At its root, Merck's Lanham Act "misrepresentation" argument mistakenly assumes the premise that mere sale of *any* product necessarily implies that it is legal; so that upon proof that the sale may be illegal in some particular, a "misrepresentation" arises that is remediable under the Lanham Act. If such reasoning were to be credited, the Lanham Act would become a "wild card" of last resort for anyone seeking to remedy alleged administrative violations. Such a result would be contrary to established standing doctrines vesting responsibility for administrative enforcement with appropriate governmental authorities in their sound discretion; rather than private, self-appointed attorneys-general. Here, the established doctrine is that FDA regulations are not enforceable by private action. *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997). That is a salutary doctrine, since FDA's policy not to interfere with U.S.

patients' private orders from Canada is politically responsive to widespread consumer demand for an alternative to high U.S. drug prices maintained by Merck (with the "PhRMA" cartel association). Hence, judgment on the pleadings may issue as a matter of law, sustaining the defense of lack of standing for Merck to allege FDA violations in a Lanham Act guise.[5]

III. SINCE MERCK DOES NOT PLEAD COGNIZABLE HARM TO CONSUMERS, ITS N.Y. GENERAL BUSINESS LAW CLAIM MAY BE DISMISSED

Merck does not—and cannot consistent with Rule 11—plead that the prescription drugs U.S. patients import from Canada are *inferior* to those available in the U.S. Indeed, those drugs include products of Merck's own Canadian subsidiary (Merck Frosst), as well as Canadian-approved generic substitutes. No issue of drug quality has been raised in the pleadings of this case. Hence, there is no issue of real harm to consumers (or the public interest) that could sustain Merck's invocation of the N.Y. Gen. Business Law, which requires such harm—not harm to Merck—as a condition precedent. *Maurizio v. Goldsmith*, 230 F.3d 518, 522 (2d Cir. 2000) (claims dismissed because conduct did not implicate New York consumer protection). Merck's N.Y. Gen. Business Law counts therefore may be dismissed on the pleadings as a matter of law. Defendants do not harm consumers, they respond to consumer orders by meeting their needs for affordable prescription drugs.

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[5] Mediplan Answer, par. 38; North Pharmacy and Pivotal Answer, par. 65; Universal Answer, par. 66.

IV. THE PLEADINGS SHOW THAT USE OF THE ALLEGED TRADEMARK ZOCOR, IS A FAIR USE.

Merck's allegations of infringing use of its alleged trademark ZOCOR, cannot overcome a fair use defense. This is ripe for decision since Merck's allegations are set forth in its pleadings and the challenged uses can be perceived from the exhibits to the Complaints.[6]

To the extent the exhibits may show that some defendants' websites mention ZOCOR as a product available to be ordered, such advertising of the availability of ZOCOR made by Merck's related company Merck Frosst is undisputedly permissible under the trademark laws. Merck's counsel has so conceded on the record, limiting Merck's trademark counts to defendants' *generic alternatives* to ZOCOR, not Canadian-sourced ZOCOR obtained from Merck Frosst itself.[7]

Sale of generic alternatives to branded products is widespread practice even in U.S. brick and mortar pharmacies, as the Court may judicially notice.[8] Sale of generic drugs is encouraged as a matter of sound public policy: New York law (and similar laws in other states) provides that unless a physician marks a prescription "d a w " (dispense

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[6] In Case No. 3650, *Merck has not pled any trademark infringement or "dilution" counts*—that case has only four counts. Hence, Merck concedes that the defendant's activity in that case does not impact Merck's alleged ZOCOR trademark rights.

[7] Hearing Transcript, June 27, 2005, p. 4, lines 5-12. Hence, the recent "gray goods" decision *Novartis Animal Health US v. Abbeyvet Export Ltd.*, 2005 WL 1649044 (SDNY 2005), has no applicability to the ZOCOR trademarked products at issue in this case. Plaintiffs conceded in the cited transcript that they assert no gray goods theory; and no issue has been raised on the pleadings about defendants' product or packaging safety.

[8] The Second Circuit observed in its recent decision *1-800 Contacts, Inc. v. WhenU.com, Inc.*: "a drug store typically places its own store-brand generic products next to the trademarked products they emulate in order to induce a customer who has

as written) in handwriting, a pharmacist should dispense a generic rather than the branded drug (saving the patient money). *NY Education Law*, Art. 137, Sec. 6810(6)(a).

Hence, there could be no valid objection to a website listing "ZOCOR generic", "generic ZOCOR" or other such words to that effect, to permit patients to purchase generic alternatives to the ZOCOR brand (Case No. 3698, Complaint Ex. C, p.8). Nor is there any valid objection to displaying generic alternatives near the brand on a website (Case No. 3696, Complaint Ex. C, p.3), which corresponds to the typical in-store placement noted with approval by the Second Circuit in *1-800 Contacts, Inc. v. WhenU.com, Inc.* (note 8, *supra*). No reasonable patient could think, and no reasonable juror could find, that "ZOCOR generic" is anything but a generic alternative to the ZOCOR brand. Such denotations are accepted lawful practice in the pharmaceutical field since consumers may not recognize the comparable nature of a generic or equivalent substitute without use of the holder's mark: *e.g.*, *G.D. Searle & Co.* v. *Hudson Pharmaceutical Corp.*, 715 F.2d 837, 842 n.12 (3d Cir. 1983). That case followed *Saxlenher v. Wagner*, 216 U.S. 375 (1910), in holding that a competitor was entitled to use the trademark owner's famous METAMUCIL® mark by name as part of the phrase "equivalent to METAMUCIL®", in promoting another laxative product as an alternative—rather than the chemical name of the active ingredient, because use of the chemical name "would not convey enough information for those consumers whose identification of the laxative they trust is geared not to its ingredients but rather to the

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specifically sought out the trademarked product to consider the store's less-expensive alternative." 2005 WL 1524515, 75 U.S.P.Q.2d 1161 (2d Cir. 2005).

popular designation METAMUCIL." Such a fair use, being lawful activity, is neither a trademark infringement nor any "dilution" of Merck's asserted ZOCOR mark.

Merck's charges of trademark infringement and unfair competition due to use of ZOCOR as a website keyword, or to trigger sponsored web advertisements (labeled as such), are similarly unfounded. The Second Circuit definitively rejected such charges in its recent decision *1-800 Contacts, Inc. v. WhenU.com, Inc.* (note 8, *supra*), holding that use of trademarked term as a keyword to trigger pop-up ads is a permissible use, not an infringement or other unlawful use.

To the extent Merck's opposition brief might seek to invoke notions of a hairsplitting difference between saying something like "Zocor generic" (allegedly bad; see Case No. 3698, Complaint Ex. C, p.8); and wordier expressions like "a generic alternative to ZOCOR" (presumably good beyond dispute), such hairsplitting runs afoul of the Second Circuit's *NBA* ruling that unfair competition law does not concern itself with *minutiae*; as well as Justice Holmes' teaching that "a trademark is not *taboo*".[9] Defendants are entitled to advertise generic alternatives to ZOCOR in any of a multitude of reasonable ways that so describe their products, without necessitating continual involvement of this Court in a hairsplitting supervisory exercise.

[9] *Prestonettes v. Coty*, 264 U.S. 359, 368; 44 S.Ct. 350; 68 L.Ed. 731 (1924).

V. CONCLUSION

For the reasons above stated, judgment may issue on the pleadings pursuant to Rule 12(c), F.R.Civ.P., dismissing Merck's allegations of trademark and unfair competition violations (Counts II *et seq.*).

Respectfully submitted,

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Dated: New York, New York
July 22, 2005

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing:

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTIONS TO DISMISS COUNTS II *ET SEQ.*

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